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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,354	01/14/2004	Bradley P. Glassman	025562.0012-US01	3208

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,354	GLASSMAN ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N Sheikh

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response Non-Final Office Action and Applicant's Arguments/Remarks, all filed 08/10/06 is acknowledged.

Applicant has overcome the following rejection by virtue of persuasive remarks: The new matter rejection under 35 U.S.C. 132(a) for the phrase "urea as the sole active antifungal ingredient."

Claims 1-13 are pending in this action. No claims have been amended, added or cancelled. Claims 1-13 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun *et al.* (WO 96/19186) in view of Chodosh (U.S. Pat. No. 5,661,170).

Sun *et al.* ('186) teach a method of treating fungal diseases in nails comprising administering to the nail a composition comprising: a) urea in an amount from about 1% to about 50%; b) an antioxidant consisting of 10.0% N-acetyl-1-cysteine; and c) mineral oil in amounts of 3.0% (see Abstract; (page 3, lines 13-24); (page 7 lines 6-20); (pg. 8, lines 16-31); (pg. 10, lines 41-46); Tables at pages 14-21 and Formulations D-K at pages 29-31.

Sun *et al.* teach antioxidants such as N-acetyl-1-cysteine. Sun *et al.* do not teach Vitamin E.

Chodosh ('170) teaches antimicrobial compositions and methods for using said compositions for treating bacterial infections of the nails or for treating onychomycosis, comprising Vitamin E, which is an antioxidant known for protecting cells from oxidation. The Vitamin E can function as a moisturizer or humectant (see reference column 2, lines 48-59); (col. 5, lines 47-67). The compositions can be applied as a gel, lotion, ointment, salve, paste or cleanser (col. 7, lines 15-43).

Both references teach a composition comprising urea, an antioxidant and excipients, which are known for treating onychomycosis or bacterial infections of the nails. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)).

One having ordinary skill in the art would have been motivated to prepare a third composition by including Vitamin E in the Sun *et al.* document, because a third composition can be used for the same purpose for treating bacterial infections or fungal diseases of the nails, and one would expect to achieve similar beneficial results. It would therefore have been obvious to combine the teachings of Sun *et al.* within Chodosh. The expected result would be a method for treating onychomycosis comprising applying to nail(s), a composition comprised of urea, Vitamin E and excipient(s).

Response to Arguments

Applicant's arguments filed 08/10/06 have been fully considered and were found to be partially persuasive.

- **New Matter Rejection under 35 U.S.C. 132(a):**

Applicant's arguments relating to the new matter rejection for the phrase "urea as the sole active antifungal ingredient" have been considered and were found persuasive. Accordingly, the new matter rejection has been withdrawn.

- **Rejection under 35 U.S.C. §103(a):**

Applicant argued, "The Sun PCT teaches using urea as a permeation enhancer to enhance permeation of an antifungal agent, such as itraconazole, ketoconazole, or miconazole nitrate. Urea is not even listed among antifungal drugs that can be used in the invention, described in the Sun PCT (page 7, lined 35 to page 8, line 5). Nowhere in the Sun PCT is there recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis. Thus, in contrast to the claimed invention, the Sun PCT does not teach or suggest urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis.

The Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis. Nowhere in the Chodosh patent is there any mention of 'urea' as opposed to the preservatives 'imidazolidinyl urea' and 'diazolidinyl urea',

much less any mention of urea as an effective antifungal ingredient. Thus, the independent claims patentably distinguish the present invention over the Sun and Chodosh documents, whether those documents are taken individually, or in combination. Neither the Sun PCT nor the Chodosh patent would have caused one of ordinary skill in the art to think that urea could be used as the sole active antifungal ingredient in a composition therapeutically effective for the treatment of onychomycosis."

Applicant's arguments have been fully considered but they are not persuasive. Applicant's argument that "Nowhere in the Sun PCT is there a recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis" was not persuasive since Sun et al. vividly teach the use of 'urea' for effectively treating nail fungal diseases, especially onychomycosis. Since the prior art clearly teaches the use of the same component, the beneficial results and properties imparted by that particular component, would also be the same. The particular component in this case being urea. Moreover, the Examiner notes that it is not necessary that the prior art teach each and every property which accrues from a particular ingredient, but merely that the prior art teach the same component for a similar field of endeavor is sufficient. Regarding Applicant's argument that "Sun et al. do not teach urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis", the Examiner points out that Applicants have not yet demonstrated that the inclusion of additional ingredients would render the composition of Sun detrimental for use in the instant invention. It remains the position of the Examiner that the prior art explicitly teaches a similar method for treating nail fungal conditions,

such as onychomycosis, by incorporating similar components that are used for the same field of endeavor as that desired by Applicant. No unexpected or superior results have been shown which distinguish over the teachings of the prior art of record.

Applicant's argument that "The Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis" has been fully considered but was not found persuasive. The Chodosh patent was relied upon for the teaching of the use of vitamin E in antimicrobial and antifungal compositions and relied upon to demonstrate that it is well known in the art to employ antioxidants, such as vitamin E, to effectively treat antimicrobial or antifungal conditions, such as onychomycois, to a subject in need thereof. The Chodosh patent was not relied upon for the teaching of 'urea' since the Sun et al. PCT initially meets this requirement of employing urea in antifungal formulations and methods. Thus, since Chodosh explicitly teaches the incorporation of vitamin E in antifungal compositions and methods for treating thereof and teaches that beneficial results are attained therewith, ample motivation has been provided by the prior art. It remains the position of the Examiner that Applicants have not demonstrated any unusual and/or unexpected results through the instantly claimed combination of ingredients. The prior art explicitly teaches similar methods of treating onychomycosis by topical application of urea, antioxidants (*i.e.*, vitamin E) and excipients (*i.e.*, mineral oil).

Applicant argued, "The Examiner has not established that the cited references disclose or suggest "urea as the sole active antifungal ingredient" as recited in all the claims".

Admittedly, while urea was not disclosed as the 'sole antifungal ingredient' in the references cited by Examiner, the references still recognize and teach general formulations

intended for treating various nail conditions, such as onychomycosis, whereby the references employ similar components, namely, antifungal agents, antioxidants, vitamins, minerals and the like, as these are art-known ingredients routinely used in cosmetic preparations.

Applicant submits, "Because the Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. 103(a), Applicants need not submit evidence of unexpected results to rebut it."

The Examiner points out that the claims at present do not distinguish over the art of record since the claims do not yet establish specific formulations with specified amounts of each ingredient claimed. The claims remain broad enough to read on the teachings of the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

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PRIMARY EXAMINER
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Primary Examiner

Art Unit 1615

November 10, 2006

hns